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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/446,783

05/16/2000

NEIL P. DESAI

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EXAMINER

VU, JAKE MINH

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

02/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/446,783	Applicant(s) DESAI ET AL.	
	Examiner JAKE M. VU	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 31 October 2007.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 73 and 74 is/are pending in the application.

 4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 73 and 74 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Information Disclosure Statement and Request for Continued Examination filed on 10/31/2007.

- Claims 73 and 74 are pending in the instant application.

Claim Rejections - 35 USC § 112

Claim 73 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of the terms "inter-molecular disulfide bond" are disclosed at lines 21-23 of page 46 in the Specification.

Double Patenting

Claims 73 and 74 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over U.S. Patent No. 6,537,579; 5,362,478; 5,498,421; 5,505,932; 5,508,021; 5,512,268; 5,635,207; 5,639,473; 5,650,156; 5,665,382; 5,665,383; 5,916,596; 5,560,933; and 5,439,686 **are maintained** for reasons of record in the previous office action filed on 01/03/2007.

Note, it is acknowledged that Applicant will address these rejections when the pending claims are found allowable.

Claim Rejections - 35 USC § 102

Claims 73 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by LIVERSIDGE et al (US 5,399,363) in light of MARKUS et al (cited supra) **are**

maintained for reasons of record in the previous office action filed on 01/03/2007 and 10/02/2007.

Applicant argues that the Examiner has provided no evidence to suggest that the methods, as disclosed in LIVERSIDGE, would necessarily result in the production of compositions comprising albumin that is crosslinked by intermolecular disulfide bonds. For example, the techniques such as sonication can be performed under different conditions, such as different energy levels, wherein LIVERSIDGE is completely silent with respect to energy level used. The Examiner finds this argument unpersuasive, because LIVERSIDGE teaches using ultrasonic energy having a frequency of 20-80kHz for a time of about 1 to 120 seconds (see col. 6, line 58-60), which is within the range of Applicant's setting of 40kHz for 60 seconds (see pg. 51, Example 19). Additionally, LIVERSIDGE teaches high shear media milling can decrease the milling time from five days or longer to times of one minute (see col. 6, line 34-39), this would disclosed to one of ordinary skill in the art to increase the shearing force, which would inherently result in the intermolecular crosslinking.

Applicant argues that the LIVERSIDGE clearly states that the "individually adsorbed molecules of the surface modifier are essentially free of intermolecular crosslinkages". The Examiner finds this argument unpersuasive, because LIVERSIDGE's "essentially free of intermolecular crosslinkages" refers to the non-intermolecular crosslinkages prior to the high shear milling and ultrasonication similar to Applicant's albumin prior to high shear milling.

Telephonic Inquiries


Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/

Jake M. Vu, PharmD, JD
Art Unit 1618

Application Number 	Application/Control No. 09/446,783	Applicant(s)/Patent under Reexamination DESAI ET AL.	
	Examiner JAKE M. VU	Art Unit 1618	